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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,389	07/12/2001	Stephanie K. Clendennen	54257-8029.US00	1613

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,389

Applicant(s)

CLENDENNEN ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I. claims 1-12 and 14 in Paper No. 7 is acknowledged.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed August 9, 2002, Paper No. 5, is attached to the instant Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-6, 8-12 and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to isolated nucleic acid molecules wherein the nucleic acid sequence has at least 85% sequence identity to the coding region of SEQ ID NO:1 or a nucleic acid encoding SEQ ID NO:2, wherein the nucleic acid sequence hybridizes under moderate to high stringency conditions to SEQ ID NO:1, wherein the nucleic acid sequence is a fragment that encodes a protein having the activity of a constitutive triple response protein, wherein the nucleic

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acid sequence has at least 90% sequence identity to SEQ ID NO:1, wherein the nucleic acid sequence has at least 85% sequence identity to nucleotides A-3286 of SEQ ID NO:1 where A is any one of nucleotides 1440-1444, and wherein the nucleic acid encodes a protein having at least 85% sequence identity to SEQ ID NO:2.

The specification describes a cDNA of SEQ ID NO:1 obtained from the melon *Cucumis melo* and encoding the amino acid sequence set forth in SEQ ID NO:2 (sequence listing). The specification also describes the amino acid sequence set forth in SEQ ID NO:2 as having homology to known constitutive triple response proteins from tomato and *Arabidopsis* (page 33). The specification also discloses that a fragment comprising nucleotides A-3286 of SEQ ID NO:1, where A is any one of nucleotides 1440-1444, has the activity of a constitutive triple response protein when expressed in a transgenic plant (page 34). The specification does not describe the structure of any nucleotide sequence encoding any amino acid sequence other than SEQ ID NO:2. The specification does not describe the structure of any nucleotide sequence having at least 85% sequence identity to the coding region of SEQ ID NO:1 or the coding region of a nucleic acid encoding SEQ ID NO:2 and which encodes a functional protein. The specification does not describe the structure of any nucleotide sequence that hybridizes under moderate to high stringency conditions to SEQ ID NO:1 and which encodes a functional protein. The specification does not describe the structure of any nucleotide sequence that wherein the nucleic acid sequence has at least 90% sequence identity to SEQ ID NO:1, or wherein the nucleic acid sequence has at least 85% sequence identity to nucleotides A-3286 of SEQ ID NO:1 where A is any one of nucleotides 1440-1444, and which encodes a functional protein. The

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specification does not describe the structure of any functional protein having at least 85% sequence identity to SEQ ID NO:2, or a nucleotide sequence encoding such a protein.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed product, any method of using it would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

Claims 1-12 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid of SEQ ID NO:1, a nucleic acid encoding

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SEQ ID NO:2, and the fragment of SEQ ID NO:1 exemplified in the vector pAG4225, as well as for plant expression vectors, plant cells and plants comprising said nucleic acids, does not reasonably provide enablement for other nucleic acid sequences or for plant expression vectors, plant cells and plants comprising said other nucleic acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to isolated nucleic acid molecules wherein the nucleic acid sequence has at least 85% sequence identity to the coding region of SEQ ID NO:1 or a nucleic acid encoding SEQ ID NO:2, wherein the nucleic acid sequence hybridizes under moderate to high stringency conditions to SEQ ID NO:1, wherein the nucleic acid sequence is a fragment that encodes a protein having the activity of a constitutive triple response protein, wherein the nucleic acid sequence has at least 90% sequence identity to SEQ ID NO:1, wherein the nucleic acid sequence has at least 85% sequence identity to nucleotides A-3286 of SEQ ID NO:1 where A is any one of nucleotides 1440-1444, and wherein the nucleic acid encodes a protein having at least 85% sequence identity to SEQ ID NO:2, as well as for plant expression vectors, plant cells and plants comprising said nucleic acids.

The specification discloses the isolation from the melon *Cucumis melo* of a cDNA of SEQ ID NO:1 encoding the amino acid sequence set forth in SEQ ID NO:2 which has homology to known constitutive triple response proteins from tomato and *Arabidopsis* (pages 32-33). The specification also discloses that plants transformed with a vector comprising SEQ ID NO:1 (pAG4224), or a vector comprising nucleotides A-3286 of SEQ ID NO:1 where A is any one of nucleotides 1440-1444 (pAG4225), exhibit an attenuated response to ethylene as compared to

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wild type control plants (pages 33-35 and Figure 3). The specification does not disclose which of nucleotides 1440-1444 constitutes nucleotide A in the fragment comprising nucleotides A-3286 of SEQ ID NO:1. The specification does not disclose or characterize any novel nucleotide sequence encoding any amino acid sequence other than SEQ ID NO:2 that affects the response of a transgenic plant to ethylene. The specification does not disclose the isolation or characterization of any nucleotide sequence having at least 85% sequence identity to the coding region of SEQ ID NO:1 or the coding region of a nucleic acid encoding SEQ ID NO:2 that affects the response of a transgenic plant to ethylene. The specification does not disclose the isolation or characterization of any nucleotide sequence that hybridizes under moderate to high stringency conditions to SEQ ID NO:1 and that affects the response of a transgenic plant to ethylene. The specification does not disclose the isolation or characterization of any nucleotide sequence has at least 90% sequence identity to SEQ ID NO:1, or that has at least 85% sequence identity to nucleotides A-3286 of SEQ ID NO:1 where A is any one of nucleotides 1440-1444, that affects the response of a transgenic plant to ethylene. The specification does not disclose the isolation or characterization of any protein having at least 85% sequence identity to SEQ ID NO:2 that affects the response of a transgenic plant to ethylene.

Guidance for making and using the claimed invention is necessary for enablement because it is unpredictable whether a nucleotide sequence other than SEQ ID NO:1 or a nucleotide sequence encoding SEQ ID NO:2, or a fragment of SEQ ID NO:1 other than that exemplified in the vector pAG4225, will encode a functional polypeptide. A change in as few as one nucleotide in a nucleotide sequence, such as would occur by truncation, hybridization or as a consequence of percent homology, can alter the amino acid sequence of the polypeptide it

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encodes, and a change in as few as one amino acid in a polypeptide can alter or eliminate its function. For example, Rhoads et al. (J. Biol. Chem., November 1998, Vol. 273, No. 46, pages 30750-30756) teach that mutation of Cys-128 to Ala in an *Arabidopsis* alternative oxidase caused a pronounced overall increase in enzyme activity relative to the wild-type in the presence or absence of pyruvate (page 30753 Figure 3). Mutation of Cys-78 to Ala in the same *Arabidopsis* alternative oxidase resulted in a minimally active enzyme that showed no response to added pyruvate (page 30753 Figure 3).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, it would require undue experimentation for one skilled in the art to determine which of the claimed isolated nucleic acid molecules would encode a functional and therefore useful polypeptide.

Remarks

No claim is allowed.

Claims 1-12 and 14 are deemed free of the prior art given the failure of the prior art to teach or suggest a ^{isolated} nucleotide sequence of SEQ ID NO:1 encoding an amino acid sequence of SEQ ID NO:2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

December 18, 2002

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